

Appl. No. 10/807,974  
Dated: April 7, 2009  
Reply to Office action of January 7, 2009

### **REMARKS**

Claims 1-9, 20-26, and 34-38 were before the Examiner for consideration, Claims 10-19, 27-33, and 39-72 having been previously withdrawn. In this paper, Claim 1 has been amended, Claims 39-47 have been canceled without prejudice as being directed to non-elected subject matter, and Claims 73-76 have been added. Accordingly, Claims 1-9, 20-26, 34-38, and 73-76 remain before the Examiner for consideration. No new matter has been added with these amendments.

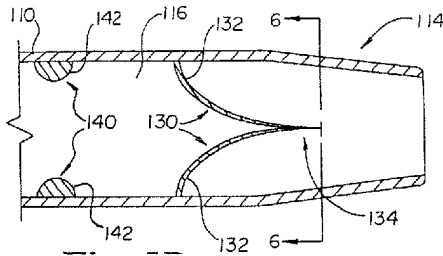
#### **Regarding the Rejections in View of Lafontaine**

In the Office Action, Claims 1-9, 20-24, and 34-38 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lafontaine (U.S. Patent No. 6,520,939). Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Green et al. (U.S. Patent No. 6,497,716). For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve 140 is normally open to allow devices to freely pass therethrough, and comprises a

flexible polymeric O-ring sized to create either an interference fit or a gap fit with a device inserted therethrough. (Lafontaine, col. 4, lines 47-64).

**Fig. 5A**



Claim 1 relates to a surgical access device comprising, among other limitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. The septum seal comprises, among other limitations, "an elastomeric sheet and an aperture through the elastomeric sheet."

Lafontaine fails to disclose all of the elements of the recited surgical access device. For example, Lafontaine fails to disclose a septum seal comprising an elastomeric sheet and an aperture through the elastomeric sheet, as is recited in Claim 1. Rather, as noted above, Lafontaine discloses a passive hemostasis valve comprising an O-ring that does not include an elastomeric sheet. (See, e.g., Lafontaine, Figure 5A)

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 2-9, 20-24, and 34-38 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. Therefore, Claims 2-9, 20-24, and

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34-38 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Green et al. Claims 25 and 26 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, Lafontaine fails to disclose or suggest all of the limitations of Claim 1. Green likewise fails to disclose or suggest the deficiencies of Lafontaine with respect to Claim 1. Green relates to a safety trocar with a sharp cutting tip that retracts into the cannula to minimize the likelihood of inadvertent injury to tissue. (Green, col. 1, lines 17-20). Green fails to disclose or suggest a "septum seal" that is coupled to a zero seal as recited in Claim 1. Rather, for gas sealing, Green only discloses a gasket positioned in a lower cannula housing. (Green, col. 5, lines 10-12).

Furthermore, Lafontaine teaches away from using a "gasket" seal with the device disclosed therein. In connection with the background to the Lafontaine device, Lafontaine does describe a "gasket" having a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures 2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets

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as either an active hemostasis valve or a passive hemostasis valve in the described surgical access device. Accordingly, one of skill in the art would be dissuaded from modifying the Lafontaine device to include a "gasket" type seal as described therein.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.

### **New Claims**

New Claims 73-76 have been added herewith to further define the inventive subject matter of the present Application. Claims 73-76 each depend from Claim 1 and recite additional novel and nonobvious limitations thereon. Accordingly, these claims are likewise distinguishable over the applied art for at least the reasons discussed above with respect to Claim 1.

### **Conclusion**

For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of

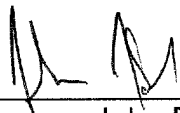
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the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

BY  \_\_\_\_\_  
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